## The Federal Register Online Via GPO Access; Public Meeting for Federal, State and Local Agencies, and Others Interested in a Demonstration of GPO Access, the Online Service Providing the Federal Register and Other Federal Databases

The Superintendent of Documents will hold a public meeting for Federal, state, and local government agencies, and others interested in an overview and demonstration of the Government Printing Office's online service *GPO Access,* provided under the Government Printing Office Electronic Information Access Enhancement Act of 1993 (Public Law 103–40).

The session is available on Wednesday, April 5, 1995, from 1 p.m. to 2:30 p.m. The training session will be held at the Dallas Public Library, Library Auditorium, 1515 Young Street, Dallas, Texas 75201.

The online **Federal Register** Service offers access to the daily issues of the **Federal Register** by 6 a.m. on the day of publication. All notices, rules and proposed rules, Presidential documents, executive orders, separate parts, and reader aids are included in the database as ASCII text files, with graphics provided in TIFF format. The online **Federal Register** is available via the Internet or as a dial-in service. Historical data is available from January 1994 forward.

Other databases currently available online through *GPO Access* include the *Congressional Record; Congressional Record Index,* including the *History of Bills;* Congressional Bills; Public Laws; and *U.S. Code.*

Individuals interested in attending the training session should contact the GPO's Office of Electronic Information Dissemination Services, John Berger, Product Manager, on 202–512–1525; (FAX) 202–512–1262; or by Internet e-mail at help@eids05.eids.gpo.gov. Seating reservations will be accepted through Friday, March 31, 1995.

**Michael F. DiMario,**

*Public Printer.*

[FR Doc. 95–5940 Filed 3–9–95; 8:45 am]

**BILLING CODE 1505–02–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 92D–0039]**

## Animal Drug Manufacturing; Revised Guideline; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the revised four-part guideline entitled, ''Animal Drug Manufacturing Guidelines, 1994'' prepared by the Center for Veterinary Medicine (CVM). These guidelines describe the data and information for the manufacturing portions of abbreviated new animal drug applications, new animal drug applications, and supplements for pharmaceutical dosage forms.

**DATES:** Written comments on these guidelines may be submitted at any time.

**ADDRESSES:** Submit written requests for single copies of the revised guidelines entitled, ''Animal Drug Manufacturing Guidelines, 1994: I. Pilot Batch Manufacture, II. Tentative Expiration Dates, III. Manufacturing Sites, and IV. New Animal Drug Substance Sources'' to the Communications and Education Branch (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1755. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the revised guidelines to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the revised guidelines and received comments may be seen at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** William G. Marnane, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0678.

**SUPPLEMENTARY INFORMATION:** The Food and Drug Administration (FDA) is announcing the availability of the revised four-part guideline entitled, ''Animal Drug Manufacturing Guidelines, 1994: I. Pilot Batch Manufacture, II. Tentative Expiration Dates, III. Manufacturing Sites, and IV. New Animal Drug Substance Sources'' prepared by CVM. These guidelines are intended to be used by both pioneer and generic manufacturers of veterinary drug products so that they are informed of the type of information that FDA believes will provide an acceptable submission to support the manufacturing requirements for new animal drug applications, abbreviated new animal drug applications, and supplemental applications for pharmaceutical dosage forms. In the **Federal Register** of August 21, 1992 (57 FR 37979), FDA issued a notice of availability of the four CVM guidelines entitled, ''Animal Drug Manufacturing Guidelines, 1992.'' Comments by the public were requested to be submitted at any time so that future revisions of the guidelines could be developed in consideration of the remarks.

The agency received three comments on the 1992 guidelines. The comments came from two drug manufacturers and one trade association. The 1992 guidelines have been revised as a result of these comments and from internal discussions within CVM.

Many editorial comments were made about all four guidelines. The editorial comments were adopted in the revised guidelines when the agency deemed that they were appropriate and provided clarification. Technical comments about ''Guideline I. Pilot Batch Manufacture'' focused on the CVM recommendations for the size of the test batch and the type of equipment or production facility that is appropriate for manufacturing test lots. A suggestion was made to allow bridging data in cases where the recommendations for batch size, production facility, equipment, and standard operating procedures are not practicable. Technical comments about ''Guideline II. Tentative Expiration Dates'' centered on a clarification of the definition of exaggerated storage conditions for different dosage forms and the application of expiration dating to all manufacturing sites for one drug product. Technical comments about ''Guideline III. Manufacturing Sites'' included criticisms of the definitions of the different types of manufacturing sites, the option for the agency to request bioequivalence data, and the appropriate location of sterile process validation data in the drug application. Technical comments about ''Guideline IV. New Animal Drug Substance Sources'' were made regarding the definitions of primary and alternate sources of the new animal drug substance, test batch and stability data for supplemental applications, and bioequivalence data requirements for mastitis products. All of these comments were considered in the revision of the manufacturing guidelines.

One of the most significant changes to the 1992 guidelines is to allow bridging data to be submitted when the recommendations for batch size, production facility, equipment, and standard operating procedures for pilot

batches are not practicable. The sponsor may create an alternative plan to that recommended in order to compare the bioavailability and stability characteristics of the test and production batch. Another major change to the guidelines is the provision of an alternate means by which sponsors may meet the supplemental application recommendations for alternate manufacturing sites and alternate sources of bulk drug substance when multiple NADA's and ANADA's are affected. The sponsor may request that pilot batches of representative drug products within the same dosage form class be manufactured instead of producing pilot batches of all affected drug products.

These ''Animal Drug Manufacturing Guidelines, 1994'' are not intended to be individual stand-alone documents. Much of the information presented in one guideline may be equally important to the correct interpretation of the other guidelines. Therefore, all four guidelines are being issued concurrently.

Guidelines state procedures or practices that may be useful to the persons to whom they are directed, but are not legal requirements. The agency is in the process of revising §§ 10.85(d) and 10.90(b) (21 CFR 10.85(d) and 10.90(b)). Therefore, these guidelines are not being issued under authority of present §§ 10.85(d) and 10.90(b). A person may follow the guideline or may choose to follow alternate procedures or practices. If a person chooses to use alternate procedures or practices, that person may wish to discuss the matter further with the agency to prevent an expenditure of money and effort on activities that may later be determined to be unacceptable to FDA. A guideline does not bind the agency, and it does not create or confer any rights, privileges, or benefits for or on any person. When a guideline states a requirement imposed by statute or regulation, however, the requirement is law and its force and effect are not changed in any way by virtue of its inclusion in the guideline.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guideline. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guideline and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered to determine if further revision of the guideline is necessary.

Dated: March 6, 1995.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 95–6006 Filed 3–9–95; 8:45 am]

BILLING CODE 4160–01–F

**[Docket No. 95N–0058]**

## Drug Export; Bulk Drug Substance Paclitaxel

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that NaPro BioTherapeutics, Inc., has filed an application requesting approval for the export of the bulk human drug substance Paclitaxel for formulation, filling, and packaging into Anzatax™ Injection Concentrate 30 milligrams (mg) paclitaxel in 5 milliliter (mL) vials to Australia.

**ADDRESSES:** Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

**FOR FURTHER INFORMATION CONTACT:** James E. Hamilton, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2073.

**SUPPLEMENTARY INFORMATION:** The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that NaPro BioTherapeutics, Inc., 4725 Walnut St., suite 100, Boulder, CO 80301, has filed an application requesting approval for the export of the bulk human drug substance Paclitaxel for formulation, filling, and packaging into Anzatax™ Injection Concentrate 30 mg paclitaxel in 5 mL vials to Australia. This product is indicated for the treatment of refractory ovarian cancer. The application was received and filed in the Center for Drug Evaluation and Research on October 21, 1994, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by March 20, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: March 2, 1995.

**Edward Miracco,**

*Acting Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.*

[FR Doc. 95–6005 Filed 3–9–95; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Social Security Administration

### Agency Forms Submitted to the Office of Management and Budget for Clearance

Normally on Fridays, the Social Security Administration publishes a list of information collection packages that have been submitted to the Office of Management and Budget (OMB) for clearance in compliance with P.L. 96–511, The Paperwork Reduction Act. The following clearance packages have been submitted to OMB since the last list was published in the **Federal Register** on February 10, 1995. (Call Reports